FAST Assessment and Treatment of Cardiovascular Disease: A Roadmap for Engineering and Physical Sciences Research

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Summary

Cardiovascular disease is the most common cause of death globally and places particular demands on the National Health Service due to the diverse range of treatment pathways and the chronic nature of the condition. Based on the results of a workshop organised by the EPSRC FAST Healthcare NetworksPlus, a roadmap for engineering and physical sciences research to address opportunities to improve assessment and treatment of cardiovascular disease has been produced. The Roadmap identifies the clinical need to provide safe, accurate, rapid and seamless care across the healthcare system in a way that is efficient and cost-effective through the optimised use of staff. This leads to two research fields.

One research field aims to improve assessment and treatment through advancement of tests (biomarkers, ECGs, ultrasound, etc.), methods for long-term monitoring and enhanced early detection of cardiovascular disease. In addition, there should be improved profiling and assessment of patients and optimised allocation of staff to delivering care. This is enabled by the development of wearable devices, algorithms for fusion, analysis and visualisation of the complex data that they produce and artificial intelligence systems for assessment. Systems-based engineering analysis is also required for implementation. This relies on the development of flexible and large-area electronics, sensor and imaging technologies and high energy density power storage and energy harvesting devices.

The second research field leads to the realisation of smart stents and artificial hearts. This requires the development of remote surgery systems and 3D printed medical devices. These in turn rely on research into robotics, nanorobotics, 3D printing techniques and 3D bio-compatible materials.

The outcomes of such a research agenda would be the optimised use of specialist and generalist-led cardiovascular disease assessment and treatment; fewer referrals between care providers and a reduced number of hospital re-admissions following discharge; better long-term treatment which is more personalised; and fast triage of individuals with cardiovascular disease into one of the seven treatment pathways.

Introduction

A key pressure on the National Health Service (NHS) is how long-term conditions, like diabetes and cardiovascular disease, are treated. Cardiovascular disease (CVD) is the most common cause of death globally. Between 2010 and 2020, it is expected that the number of people in England suffering from CVD will increase by 59,000 [1]. Around one third of the difference in life expectancy between the most affluent and deprived areas in the UK is believed to be attributable to CVD [1]. This Report aims to set out a roadmap for how research in engineering and the physical sciences can lead to a positive impact in the way that CVD is assessed and treated in public health systems. It is based on a Workshop held in Cambridge University on the 5th January 2017 which included participants from academia, clinical practice, public health management and industry.

The Report is structured into four parts, which reflects the structure of the Workshop itself. Firstly, the clinical context for the assessment and treatment of CVD is set out, focussing on current practice and known clinical challenges. This leads on to a discussion about the engineering and physical sciences opportunities that exist in this space before the barriers and enablers which lie between research being put into widespread clinical practice are considered. The role of systems-based engineering in a healthcare context is also reviewed In the final section of the report, these three elements are brought together into a holistic roadmap for the research community to use to help set out research trajectories over the coming years. .

Clinical Scenario

Background

If we are looking to make a significant impact on the assessment and treatment of CVD through engineering and physical sciences (EPS) research, then a good starting point is to bear in mind that around 85% of all CVD cases fall into four groups:

1. coronary heart disease (including heart attacks and angina);
2. heart failure (which can be because of a heart attack, but may have other origins resulting from inefficiencies in the circulatory system);
3. rhythm disorders; and
4. valve disorders (including narrow, leaking or infected valves in the heart).

Of these four areas, heart failure and valve disorders are seeing a particular increase in frequency because of the rising life expectancy in the population. If we wish to reduce the number of people presenting with CVD in the first place, then it will be necessary to identify and monitor people who are at particular risk of inherited CVD and those who are in the early stages of atherosclerosis (the build-up of fatty material inside arteries).

Acute symptoms which commonly cause people to present in the health system for the first time include chest pain as a result of a heart attack, shortness of breath due to heart failure (often associated with the left ventricle), and rhythm disorders leading to fainting, palpitations

[1] Source: *NHS England*

or cardiac arrest. Chronic symptoms are often very similar to acute symptoms but can develop incrementally with time, and it often requires a sudden step-change in how a person feels to prompt them to seek medical advice.

In practice, therefore, it can be very challenging to make an initial assessment as to whether a particular combination of symptoms is due to a cardiac condition, or something else which has a similar set of symptoms. There may also be some other underlying disease which has led to an individual's cardiac condition. Severe symptoms may also mean that assessment has to be made very rapidly.

It is in this context that assessment has to be considered. A significant number of people will present with symptoms to their general practitioner (GP) in the first instance, although more severe symptoms will often result in presentation at a hospital emergency department. Both generalist medics and specialist cardiologists therefore have roles to play in the assessment process. The generalist is often required to make an initial assessment as to whether a person has a cardiac problem or something else, and if the former what type of cardiac problem it is. The generalist may wish to initiate some investigations in order to make this initial assessment, and this raises a question as to what types of investigations it is appropriate for a generalist to initiate as opposed to a specialist, and at what point referral to the cardiac specialist takes place to give the best clinical outcome for the person whilst ensuring efficient use of resources.

Once a person has been transferred to specialist secondary or tertiary care, they will be moved to one of seven treatment pathways: general cardiology, inherited cardiovascular conditions, heart failure, structural heart disease, heart valve disease, arrhythmia, or coronary artery disease. Some of these pathways may result in a few people undergoing high-cost treatments. A greater number of people will require some more limited corrective treatment to remove circulatory short circuits or breaks. Rehabilitation has also been shown to be effective in improving quality of life and survival rates following a heart attack, but this requires ongoing attendance by the person at specialist rehabilitation centres, and drop-out rates are known to be an issue with such programmes. Most commonly, medication is ultimately used to manage CVD over the long-term back through the primary care system.

The aim for assessment and treatment is to have a system that is based upon delivery through different care levels (primary, secondary and tertiary) that is safe, accurate, rapid, seamless from a user perspective, efficient and cost-effective. The weak points in the system lie at the transitions between the care levels. This requires exchange of data, and the links between information technology (IT) systems are notoriously hard to implement in a fashion that is secure and efficient as data is usually held on different systems that have not been designed to be interoperable at the outset.

In a manufacturing line, it is possible to optimise the efficiency of throughput by controlling the in-flow of raw materials, the through-flow of the manufacturing process and the out-flow of the finished product. In a healthcare system, however, complete control of the in-flow of people is not possible due to immediate clinical requirements of people presenting at a given moment in time. Whilst some degree of control is possible to maximise efficiency, this can be

compromised by resource shortages (such as bed shortages in tertiary care or limited social care availability in the primary sector). It should also be noted that people are the most expensive resource in the healthcare system, and an efficient system ensures that all individuals involved in delivering healthcare are being used optimally within their competence.

Clinical Roadmap

Figure 1 shows a roadmap of desirable clinical developments over the coming 12 years based on the Workshop. Although there are many specific developments, it is possible to draw together some common themes that are driven by the specific requirements of CVD assessment and treatment.

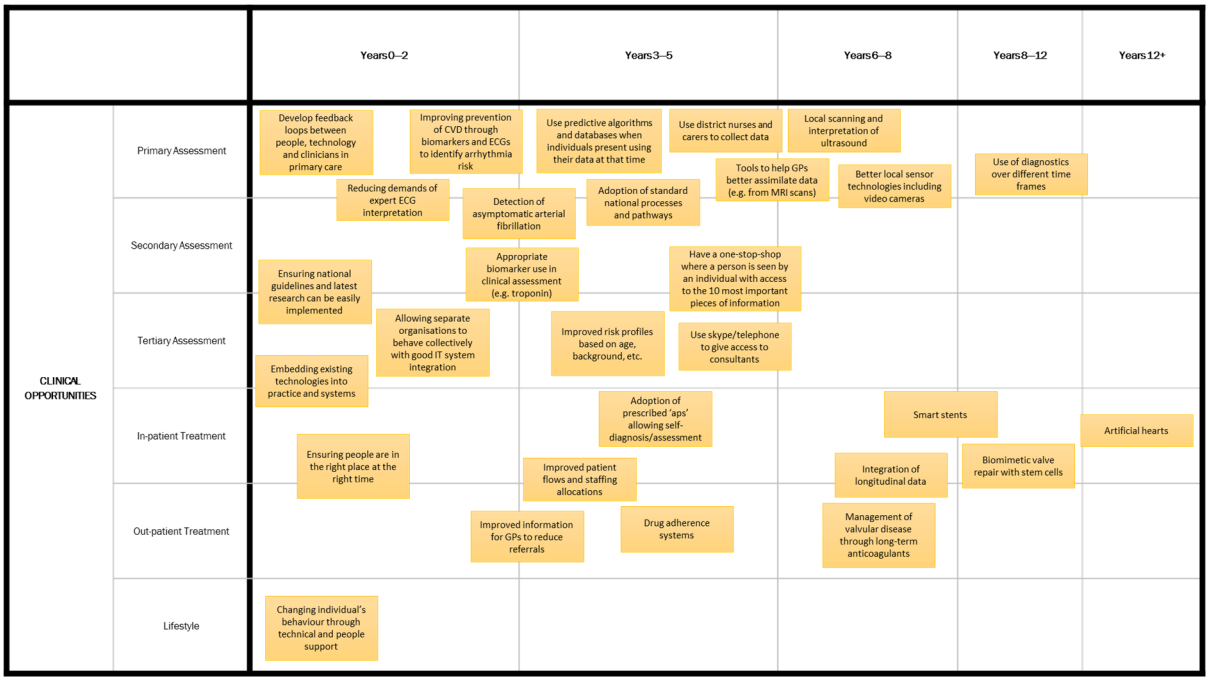

FIGURE 1. ROADMAP OF THE CLINICAL OPPORTUNITIES IN CVD ASSESSMENT AND TREATMENT OVER A 12 YEAR PERIOD.

GPs have a critical role in the assessment of individuals, both those with clinical symptoms, and also before the presentation of symptoms. Their role can be enhanced through better provision of information. One aspect of this is the availability of data, such as through the measurement of biomarkers, electrocardiograms (ECGs) and ultrasound with better sensor technologies. However, tools to assist in the interpretation of the raw data will also be essential to reduce the likelihood of referral to specialists and the consequent transition to secondary or tertiary care. The use of predictive algorithms which can access existing databases and analyse an individual's data in that context would be a powerful tool for GPs. There is also room in this space for improving early stage detection of the onset of CVD. It may also be possible to better utilise existing contact with individuals at the primary care level (such as with district nurses or carers) to collect data over an extended time frame, and so build up a better understanding of the overall wellbeing of someone with CVD or someone who has an increased risk of developing CVD.

Some of these trends impact upon secondary and tertiary assessment as well, but there are additional developments that could have a more specific impact on these sectors, including better profiling of individuals presenting directly at hospitals, and the use of communications to give individuals access to specialists without having to visit a hospital in person.

In the area of treatment, the importance of ensuring that people and data can move through the whole of the NHS system seamlessly is a clear clinical need. Part of this is about making sure that people only make necessary transitions from primary to secondary or tertiary care, improving people flows when transitions are necessary and ensuring that individuals are in the right place at the right time. Staffing allocations are also critically important to ensure that a member of staff's time is being best used given their skills in the context of the skills of the entire staff. This is critical to having an efficient system.

A number of clinical developments are focused on what might collectively be called 'standardisation of practice', either by providing means to embed existing technologies and adherence to national guidelines into everyday clinical practice, and by improving information flow between separate NHS organisations with encouragement for individual organisations to behave for the 'collective good'.

Longer-term trends in clinical practice are more focussed on improving treatments, and would require significant fundamental EPS research. The need for long-term anti-coagulants for management of valvular disease will almost certainly require closed-loop control. Smart stents and even artificial hearts will both require major developments in the manufacturing of soft tissue structures, energy transfer and control systems.

Technological Developments

Wearable Technologies

It is clear from Figure 1 that many clinical developments in CVD will focus on assessment and treatment in the primary healthcare sector. A key development in this space is the rise of wearable devices for healthcare monitoring. One specific area in which this has already been developed is clinical trials by pharmaceutical companies. Traditionally, a clinical trial would involve periodic assessment of the individual participating on the trial by a professional, with questionnaires that are completed by the participant providing interim information. However, such questionnaires are known to be highly subjective. Wearables, both in the clinical trial and broader clinical context, provides:

- continuous data;
- objective measurement;
- the potential to identify end points;
- more data for statistical analysis and algorithm training; and
- real-world data.

This can lead to better assessment of drug effectiveness and allows differentiation of the impact of different medicines on an individual. However, wearables give rise to a number of challenges, including: regulatory requirements; clinical acceptability and subject burden; data

transmission and handling; data analytics; initial operational costs; and added complexity. There is also a limit to how many wearable devices an individual can reasonably be expected to use at any one time.

Therefore, if implementing wearables as part of either an assessment or treatment process, it is critical that the correct specific device is chosen. This means starting with a clinical hypothesis which advocates the measurement of something specific (for example, measuring breathlessness by monitoring how long an individual is able to sustain high levels of physical activity coupled with heart and respiration rates). An assessment is then needed as to whether an 'off the shelf' solution already exists, or whether a solution exists but in a pre-commercial state, or whether a solution would need to be developed from scratch. Finally, a means of transmitting data needs to be selected. At a very basic level, data can be stored on the device, which is then physically sent for analysis. Whilst this is secure, it means that real-time continuous monitoring is not possible. If the internet is used for communication, then a number of new problems emerge. Security of data transmission is a key element. However, if continuous monitoring is critical for timely medical intervention, then this implies that it must be possible to send data continuously using a reliable system. In practice, both 3G and 4G connectivity in the home environment is not sufficiently reliable, and many homes have 'dead' wi-fi areas. There is also an issue about who pays for the data transmission – should data sent over a 4G network through an individual's mobile phone be offset against that person's data allowance?

It should be remembered that there is a key difference between the use of wearables for clinical trials and that used in broader monitoring for healthcare as a result of the significantly greater quantity and diversity of data in the latter case. This makes the extraction of meaningful data far more challenging, but there are significant opportunities to abstract information of real clinical value from a large body of data by using a combination of machine learning and existing clinical expertise.

Whilst specific devices have been the focus of this discussion, it should be remembered that there are lots of non-specific lifestyle monitoring wearable devices and apps now on the market, such as the FitBit. There is the potential for these to provide a wealth of information, but it is not clear at this point how this information could be practically used. It is also known that these devices can be used to change an individual's behaviour.

Large-area and flexible electronics could play an important role on the development of wearable devices, allowing more diverse form factors for electronic systems with the result that unobtrusive patches could be integrated into clothing or directly to the skin.

Other Technological Developments for CVD

Beyond wearables, there are a number of emerging technologies that could have a significant impact upon the assessment and treatment of CVD.

3D printing is one such technology which is already finding an application in surgery. It is now possible to 3D-print models of parts of the body, such as the heart, from computerised tomography (CT) scans. This can help with the planning of surgical procedures by allowing

the surgical team to study a true 3D replica of an organ. However, the direction of travel in 3D printing is towards printing tissue itself. This would unlock the possibility of manufacturing replacement heart valves, or even printing an entire artificial heart. It should be noted that artificial hearts do already exist, but the battery packs that are associated with them are enormous and they respond slowly to changes in activity, resulting in users experiencing dizziness. These other issues also need to be addressed.

Stem cell technology is also likely to play a part in treating CVD. Induced pluripotent stem cells are those stem cells that are taken from adult tissue and which can be reverted back to a state where they can form multiple types of cells, including muscle cells in the heart [2].

Finally, there are significant developments in robotics that could find application to CVD. For example, in a hospital catheter laboratory robotics could be used to assist or even control common procedures, such as ablation. Remote surgery using robotics might also allow individuals to access specialist treatment without the need to travel long distances to specialist treatment centres. In the longer term, nanoscale robots could be used *in vivo* to remover atherosclerotic plaque from arteries.

Technological Roadmap

Figure 2 shows a roadmap of desirable technological developments over the coming 12 years based on the Workshop. As with the Clinical Roadmap, there are some common themes which emerge.

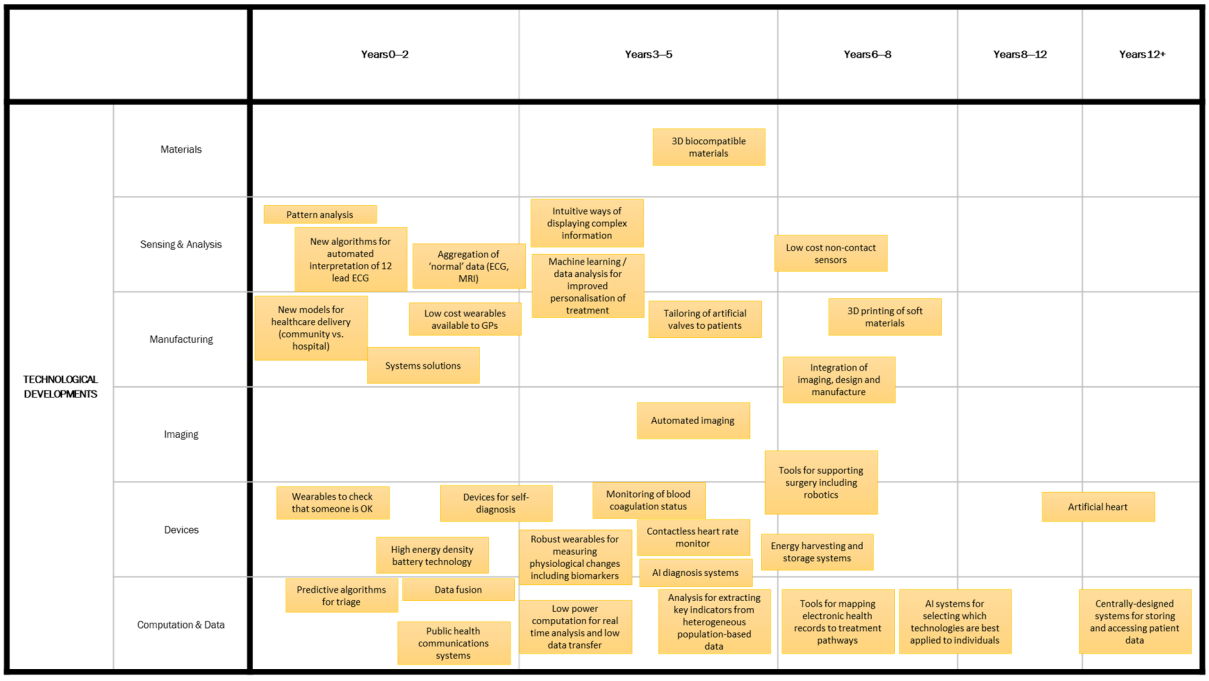

FIGURE 2. ROADMAP OF THE DESIRED TECHNICAL DEVELOPMENTS TO IMPROVE CVD ASSESSMENT AND TREATMENT OVER A 12 YEAR PERIOD.

There is a clear need for devices which enable frequent or continuous monitoring of people in everyday life. Some of these will need to be wearable, they will all need to be robust, there must be a practical way of powering them, and they must be available for GPs and other

clinicians to deploy. Specific requirements in the context of CVD include measuring blood coagulation state, heart rate (or even full ECGs) and key CVD biomarkers. Sitting alongside this is a consequent computation and data requirement. This includes talking how data is securely stored and accessed, how multiple data sources can be fused so that some form of automated diagnosis is possible or so that complex information can be represented in an accessible form. Data fusion needs to lead to better personalised treatment, with artificial intelligence-assisted mapping of an individual's state of health to specific treatment pathways having previously analysed population-based data. There may also be the opportunity to tailor manufactured artificial valves to an individual person.

Other areas that emerge from the roadmap include the need for systems-based engineering of new models for healthcare delivery than consider community and hospital-based care holistically. There is also a clear trajectory of the development of 3D biocompatible materials leading to 3D printing of such soft materials and finally the manufacture of an artificial heart by combining these materials and processes.

Barriers and Opportunities

There are enormous potential benefits to being able to gather large quantities of data at the population-level and then to use machine learning to be able to make diagnosis and assign a treatment pathway to an individual based on their personal data. A good example is the UK Biobank, which contains over 80,000 ECGs and which has been used to assist is in the diagnosis of atrial fibrillation. A single clinician will never be able to consider such a large data set, and therefore cannot take account of low probability events, whereas machine learning algorithms can include these.

There is a real opportunity for remote monitoring and self-management of CVD. A good example of this is that fact that there is a ~25% re-admission rate of people admitted to hospital with heart failure if there is not a prompt follow-up in community-based care after discharge. However, to make technological solutions work practically, they need to be designed with the target population in mind, understanding both what the users' requirements are and how they practically would use the technology. Relying purely on a technology push to lead to uptake can result in the technology being used only be those who do not need it [3].

Lessons learned from previous co-design workshops include:

- it is better not to use dedicated equipment, but to use existing tablets, etc.;
- use of icons works better than keyboards for user interaction;
- reliable systems need to be used for data collection (e.g. Bluetooth) and only known good data should be transmitted;
- users need to be given help with data interpretation;
- users need to be given easy access to tailored self-management tools, such as online videos access directly via icons; and
- machine learning is essential for setting up personalised alerts (the same algorithms should not be used for everyone).

In trying to move technology to application, it is necessary to engage with stakeholders, including industry partners. However, they all need to share the same goals. It is very easy to end up with too many stakeholders with different ambitions which can paralyse development. There also needs to be realism regarding the level of change that an existing healthcare system will tolerate. Incremental evolutionary change is much more likely to be adopted than revolutionary change. As such, new technology needs to fit in with and support existing clinical pathways.

Barrier Roadmap

Figure 3 shows the roadmap of barriers to successful impact of technology in CVD healthcare. In reality, the roadmap is fairly generic in healthcare field.

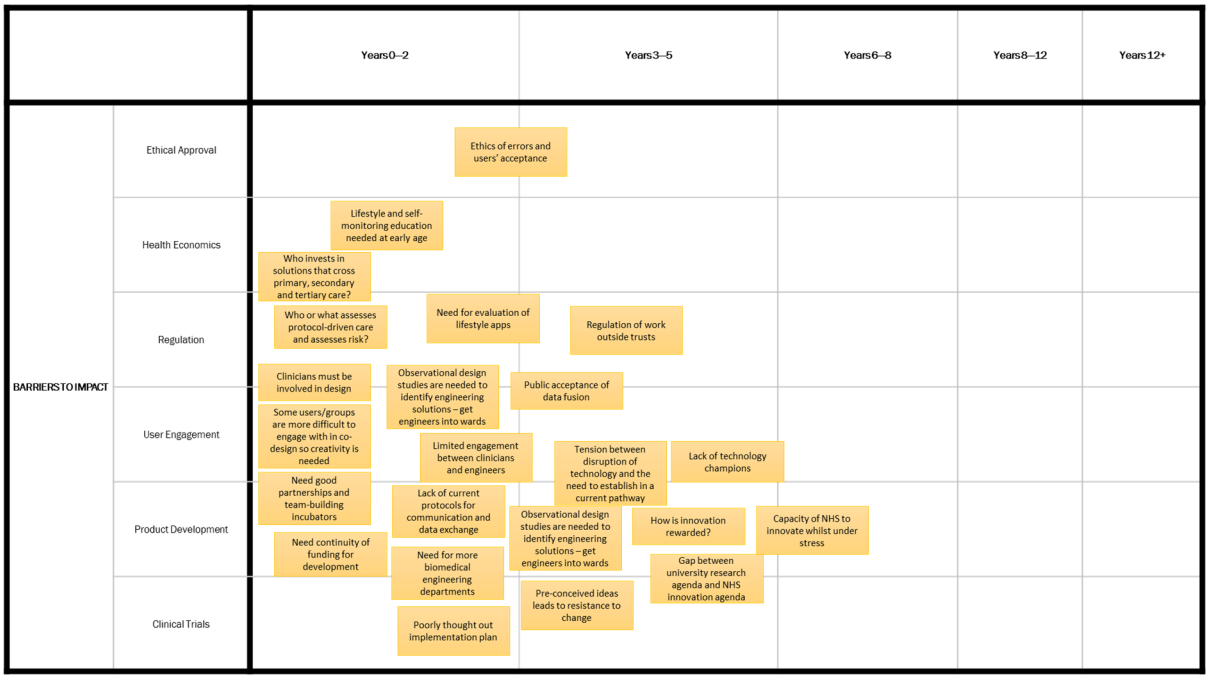

FIGURE 3. ROADMAP OF BARRIERS TO SUCCESSFUL IMPLEMENTATION OF TECHNOLOGY IN CVD ASSESSMENT AND TREATMENT.

There are a number of barriers associated with user engagement. There is a real need to get users, clinicians and engineers to work together on developing healthcare technology, and ways need to be found to incentivise this process, perhaps through the use of team-building incubators and technology champions. Getting engineers into clinical practice to observe current processes is critical. There is also a need for more engineers to work in the biomedical area and for a greater number of university departments to be devoted to this field also. Collaboration can help to ensure that pre-conceived ideas which may otherwise impede adoption of new technology are not given the opportunity to gain traction.

There are also a series of barriers associated with evaluation, whether that is assessment of protocol-driven care, lifestyle apps or technology itself, with associated regulatory processes.

Perhaps the most problematic barrier, however, is the current lack of protocols for communication and data exchange which prevents systems from sharing information, and allowing information to seamlessly follow users across healthcare providers.

The Systems-Based Engineering Opportunity

Systems-based engineering presents an opportunity to optimise the design of the healthcare system. It is based on four elements, all of which place people at their heart. The first element is 'systems thinking'. This considers the entire healthcare process from the clinician all the way to an individual's own role in their healthcare (e.g. by managing their own medication). It requires understanding of who the stakeholders are and considers how they are best organised and integrated. The second element is 'design thinking', in which real needs (as opposed to perceived problems) are identified and solutions developed that meet the real needs. The third element is 'risk thinking'. Critical risk points in a process are identified as well as the conditions which might lead to the risk might becoming reality. Mechanisms can then me put in place to mitigate the risk. The fourth element is 'people thinking' which considers who will use the system, where the system is and what affects the system, placing people first and designing the system around the people.

Engineering and Physical Sciences Research Roadmap for CVD

These individual roadmaps lead to an overarching EPS research roadmap which the FAST NetworksPlus is adopting. This roadmap is shown in Figure 4. Its structure is based upon the 'Three-Plane Diagram' developed by the National Science Foundation's Engineering Research Centers [2]. It aims to show how fundamental technology couples directly with enabling engineering to address specific clinical drivers.

The starting point for the Roadmap is a set of requirements, which are distilled from this Report to be:

- safe, accurate, rapid and seamless assessment and treatment of CVD across the primary, secondary and tertiary heath sectors; and
- efficient and cost-effective care of people with CVD which makes the best use of staff, recognising that they are the single most expensive asset in the health system.

This leads to two broad research fields. One is in the area of flexible and large-area electronics with specific sensor and imaging technologies and power systems. This enables wearable devices for continuous monitoring, which can be combined with algorithms for data fusion and interpretation, including AI to address the clinical drivers of needing improved testing, early detection and long-term monitoring and better decision making as to when care is delivered by generalists in the primary sector or specialists through the secondary and tertiary sectors. When coupled with people-focussed systems-based engineering of healthcare processes, this can allow optimisation of the use of staff to specific tasks. The second area sees two strands of technology and engineering linking together to enable smart stents and artificial hearts. One is in robotics and high energy density power storage systems enabling

[2] http://erc-assoc.org/content/three-plane-diagram

remote surgery systems. The other is in 3D printing techniques and the development of 3D bio-compatible materials to enable 3D-printed medical devices.

Such a research agenda would lead to:

- optimised use of specialist and generalist-led CVD assessment and treatment;
- fewer referrals between care providers and a reduced number of hospital re-admissions following discharge;
- better long-term treatment which is more personalised; and
- fast triage of individuals with CVD into one of the seven treatment pathways.

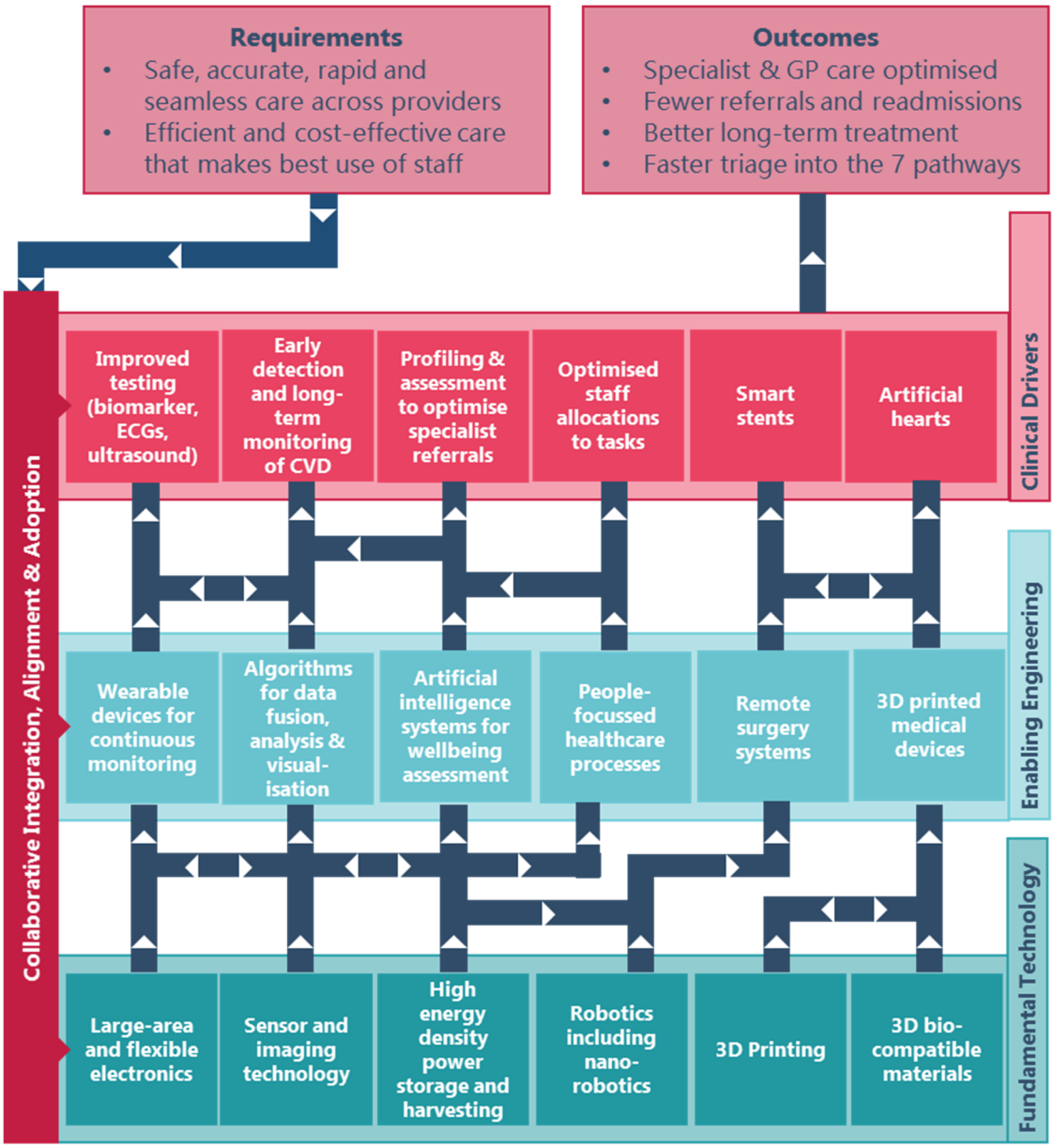

FIGURE 4. OVERARCHING ROADMAP OF EPS RESEARCH FOR OPTIMISING CVD ASSESSMENT AND TREATMENT.

Fundamental Technologies

At the base of the Roadmap are six fundamental technologies which underpin any research agenda addressing the clinical drivers. Given their importance, each is briefly considered.

- **Large-area and flexible electronics.** This is the field of electronic engineering which considers electronic devices and systems on substrates such as metal foils, plastic foils and glass. Such devices usually use thin film materials which are deposited using low temperature vacuum processes or which are produced by additive manufacturing techniques, such as printing. Large-area and flexible electronics underpins the development of devices that can be incorporated into clothing or other products, such as patches that can be applied directly to the skin.
- **Sensor and imaging technology.** There are a wealth of sensor and imaging technologies that are currently being developed for biomedical applications. Different sensing and imaging modalities are suited to certain applications. In the development of the roadmap, it was clear that there is a need for sensors for biomarkers associated with CVD (such as troponin), sensors for detecting ECG signals and potentially even ultrasound imagers that could be used more widely by non-specialists.
- **High density power storage and harvesting.** Continuous monitoring systems need power to run. However, many battery packs are bulky and require frequent charging. In addition, in some applications where devices are embedded inside the body, charging may be impractical. An extreme example of this is an artificial heart, which would need a significant, highly reliable and long-term power source. Therefore, there is a need to energy storage devices with a high power density to increase the time between charging events or to reduce the size of the battery pack. There may also be an opportunity to use energy harvesting in some low power applications to eliminate the need to charging.
- **Robotics including nanorobotics.** The Workshop identified a number of opportunities where advances in robotics could have an impact. The nearest-term example of this is for remote surgery which would allow a person to be treated by a specialist without having to be physically close to them. This could allow specialist treatment in non-specialist centres. In the longer term, nanorobotics may allow procedures to be carried out by a small robot implanted inside the body which could, again, be controlled remotely.
- **3D printing.** 3D printing is the technique by which an additive manufacturing process can be used to fabricate bespoke, complex 3D structures. As an area, it has advanced considerably in recent years with a more diverse range of materials and structures becoming possible. The challenge will be to develop 3D printing as a technique for fabricating complex structures out of biocompatible and even biological materials that are tailored to an individual, such as a replacement heart value which is designed to fit an individual.
- **3D biocompatible materials.** Associated with the development of 3D printing is the need for a greater diversity of 3D biocompatible materials which could be used as the basis for a smart stent, or in the longer term even an artificial heart. There is existing

work on a diversity of 3D scaffold materials, but these need to be manufacturable in the structures required clinically.

Acronyms

AI	Artificial Intelligence
CT	Computerised Tomography
CVD	Cardiovascular Disease
ECG	Electrocardiogram
EPS	Engineering and Physical Sciences
GP	General Practitioner
IT	Information Technology
NHS	National Health Service

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- Dr Paul Flynn (Clinical Director for Cardiovascular / Metabolic Medicine, Cambridge University Hospitals NHS Foundation Trust)
- Professor John Clarkson (Director of the Cambridge Engineering Design Centre, Engineering Department, Cambridge University)
- Dr Luis Garcia-Gancedo (gsk)
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